California Department of Health Services, Genetic Disease Branch, NBS Program
Informed Consent for Supplemental Testing Research Study

Participation, Purpose, and Procedures
You are being asked to participate in a research project conducted by the California Department of Health Services to evaluate new newborn screening tests for metabolic diseases. This additional testing will use the same blood specimen that has already been drawn for the required newborn screening test.

Description of Risks
You and your physician will only be notified if follow-up is needed for further diagnosis or treatment. If you are contacted, you will be referred to an expert and provided with information about the disease and its treatment. An unusual result does not always mean that a disorder is present. (About 90% of babies with unusual results will not have any of these disorders.) There is a small chance that these rare disorders could be missed by this test. If the specimen collected from the baby is found to be unsuitable for testing, the optional testing will not be done.

Description of Benefits
If you elect to participate in this research project, and your baby is found to have one of these disorders, early detection and treatment may prevent serious physical and mental disabilities, or even death.

You should know that for some of these disorders, current medical treatment may not be effective in preventing all of the symptoms associated with this disorder.

By participating in the study, you are helping the California Newborn Screening Program decide which disorders to add to the routine screening in the future. This will benefit newborns with these disorders.

Compensation
You will not receive any compensation to participate in this project.

Confidentiality of Records
If you decide to participate in this research project, you are consenting to the release of all medical information concerning treatment, costs, and follow-up care to the Genetic Disease Branch if a disorder is diagnosed. You might be contacted directly for some of this information if it is not available elsewhere. All information collected shall be confidential and shall not be released to anyone without your written permission, except as otherwise required or permitted by state or federal law.

Injury
Your baby will experience no additional discomfort beyond the heelstick normally done for routine newborn screening.

Questions
For any questions on this research project, you may contact your doctor or George Cunningham, MD, MPH, Chief of the Genetic Disease Branch, toll-free at (866) 954-BABY (866-954-2229) or msms@dhs.ca.gov.

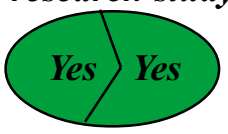
Voluntary Participation
Your participation in this research study is voluntary, and if you decline to participate, you will not lose any existing benefits or services. Your baby will continue to receive routine newborn screening.

Alternatives
If you do not wish to participate in this project but wish to have supplemental screening through a private lab, your doctor, the hospital staff, or the Genetic Disease Branch (at the above toll-free number) can assist you.

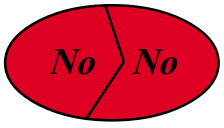
Consent
I have received and have read or had read to me a copy of the brochure *Important Information for Parents about the Newborn Screening Test*, this consent form and the *California Research Participant s Bill of Rights* and have had my questions answered to my satisfaction.

Birth hospital staff will provide you with this form, which you will then be asked to sign. Do not sign during your prenatal visits.

☐ ***Yes, I want my baby to participate in this research study.***



☐ ***No, I do not want my baby to participate in this research study.***



Parent ***Date***

Witness (optional) ***Date***

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CALIFORNIA RESEARCH PARTICIPANT'S

BILL OF RIGHTS

Any person who is asked to participate as a human subject in a research study, or who is asked to consent on behalf of another, has the following rights:

a) Be informed of the nature and purpose of the study.

b) Be given an explanation of the procedures to be followed in the study, and any drug or device to be utilized.

c) Be given a description of any attendant discomforts and risks reasonably to be expected from the study.

d) Be given an explanation of any benefits to the subject reasonably to be expected from the study, if applicable.

e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

f) Be informed of the avenues of medical treatment, if any, available to the subject after the study if complications should arise.

g) Be given an opportunity to ask any questions concerning the study or the procedures involved.

h) Be instructed that consent to participate in the study may be withdrawn at any time and the subject may discontinue participation in the study without prejudice.

i) Be given a copy of the signed and dated written consent form.

j) Be given the opportunity to decide to consent or not to consent to the study without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.